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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/449,631	11/30/1999	WOLFGANG A. RENNER	1700.0030002	6512

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EXAMINER

MOSHER, MARY

ART UNIT	PAPER NUMBER
1648	23

DATE MAILED: 11/14/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. <b>09/449,631</b>	Applicant(s) <b>Renner et al</b>
	Examiner <b>Mosher</b>	Art Unit <b>1648</b>



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1)  Responsive to communication(s) filed on 8/27/02

2a)  This action is FINAL.      2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

#### Disposition of Claims

4)  Claim(s) 50-58 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 50, 51, 54, 57, and 58 is/are rejected.

7)  Claim(s) 52, 53, 55, and 56 is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.

2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1)  Notice of References Cited (PTO-892)

4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

5)  Notice of Informal Patent Application (PTO-152)

3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

6)  Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 102***

Claims 50, 51, 54, 57, and 58 are rejected under 35 U.S.C. 102(e) as being anticipated by Birkett 6,231,864, for reasons of record. Applicant argues that haptens are conjugated in a random fashion to reactive residues in the engineered core, in contrast to the instant invention where determinant and scaffold are brought together through association of first and second attachment sites to form an ordered and repetitive array. However, the specification defines “association” as referring to any non-peptide bond (page 11), and the reference teaches bringing together a hapten and a “scaffold” with a non-peptide bond. Applicant cites Birkett as stating that approximately 50 percent of the strategically modified Hbc monomers were operatively linked to hapten, whereas only 5 percent of the wild-type Hbc particles were linked to hapten, and argues that Birkett merely teaches increased coupling efficiency. Applicant argues that the close spatial arrangement of spikes does not indicate display in an ordered and repetitive array; the examiner does not understand this argument. Spikes on the HBV core particle are inherently arranged in an ordered and repetitive array; there is at least 10-fold increase in hapten attachment when a coupling site is engineered at the tip of the spike; the hapten appears to be attached at one hapten per spike (on average), and logic dictates that steric hindrance would reasonably prevent attachment of more than one hapten per spike (consistent with Birkett’s finding of 50 percent linkage of hapten to monomer, since there are two monomers per spike). Therefore there seems to be ample reason to believe that at least 90% of the haptens bound to each particle are attached

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to the coupling site at the tip of the spikes, and that most or all of the spikes have a coupled hapten. Therefore it is concluded that Birkett's particles do display the hapten in an ordered and repetitive array, and the rejection is maintained.

*Allowable Subject Matter*

Claims 52, 53, 55, 56 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following art is cited as of interest, as disclosing virus-like particles containing antigens attached via biotin linkers: Mueller et al 6,380,364; Schiller et al 2002/00081295 (see especially paragraphs 0046-0052; ordered arrays are explicitly disclosed in paragraph 0047); as disclosing HBC particles containing antigens attached by capsid-binding peptides: Murray et al 2002/0064533.

*Conclusion*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR

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1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is (703) 308-2926. The examiner can normally be reached on Monday - Thursday and alternate Fridays from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is now (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

November 13, 2002

*Mary Mosher*  
MARY E. MOSHER  
PRIMARY EXAMINER  
GROUP 1800  
1600